

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.1082(b) is amended by adding a new subparagraph, as follows:

§ 121.1082 Modified hop extract.

(b)

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, n-butyl alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of n-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in § 121.1203 except that the boiling point range for light petroleum spirits is 150° F. to 300° F.

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1))

Dated: November 3, 1970.

R. E. DUGGAN,
Acting Associate Commissioner
for Compliance.

[F.R. Doc. 70-15268; Filed, Nov. 12, 1970;
8:46 a.m.]

PART 128a—FISH AND SEAFOOD PRODUCTS

Subpart A—Smoked and Smoke-Flavored Fish

Current good manufacturing practice (sanitation) in manufacture, processing, packing, or holding of smoked and smoke-flavored fish for human food.

In the FEDERAL REGISTER of October 23, 1969 (34 F.R. 17176), the Commissioner of Food and Drugs proposed regulations (Subpart A, Part 128a) covering current

good manufacturing practice (sanitation) in the manufacture, processing, packing, or holding of smoked fish. In response, comments were received from two trade associations, eight manufacturers, and the Bureau of Commercial Fisheries, Department of Interior. The comments include opposition to certain requirements and suggestions for clarifying and technical changes.

The principal objection is that the process requirements in the proposed regulations cannot be applied to all species of fish presently being smoked by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis.

The Commissioner finds: (1) That although adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of *C. botulinum* Type E; and (2) that since the public health hazard of *C. botulinum* Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay.

Therefore, having considered the comments received and other relevant material, the Commissioner concludes that the proposed regulations, with most of the suggested clarifying and technical changes incorporated, should be adopted as set forth below. Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), the following new Subpart A is added to Part 128a:

Subpart A—Smoked and Smoke-Flavored Fish

- Sec.
- 128a.1 Definitions.
- 128a.2 Current good manufacturing practice (sanitation).
- 128a.3 Plants and grounds.
- 128a.4 Equipment and utensils.
- 128a.5 Sanitary facilities and controls.
- 128a.6 Sanitary operations.
- 128a.7 Processes and controls.

AUTHORITY: The provisions of this Subpart A issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a).

§ 128a.1 Definitions.

(a) **Smoked fish.** As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.

(b) **Smoke-flavored fish.** As used in this part, the term "smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke. This paragraph does not alter the labeling requirements under § 3.201 of this chapter.

(c) **Loin muscle.** As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(d) **Water phase salt.** As used in this part, "Water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th edition, page 273 (1965), multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of said edition.

(e) **Hot-process smoked or hot-process smoke-flavored fish.** As used in this part "hot-process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraphs (a) and (b) of this section to heat as prescribed in § 128a.7(b).

§ 128a.2 Current good manufacturing practice (sanitation).

(a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this Subpart A set forth additional requirements for the hot-process smoked or hot-process smoke-flavored fish industry.

§ 128a.3 Plants and grounds.

(a) Unloading platforms shall be:

- (1) Made of readily cleanable material.

- (2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes should be carried out in separate rooms or facilities, and the interior walls separating these processes should extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

- (1) Receiving or shipping.
- (2) Storage of raw fish.
- (3) Presmoking operations (thawing, dressing, brining, etc.).
- (4) Drying and smoking.

(c) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

- (1) Cooling and packing.
- (2) Storage of final product.
- (d) The product shall be so processed as to prevent contamination by exposure to areas, utensils, or equipment involved

in earlier processing steps, refuse, or other objectionable areas.

§ 128a.4 Equipment and utensils.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature-measuring devices shall have an accuracy of $\pm 2^\circ \text{F}$.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents.

(c) Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

§ 128a.7 Processes and controls.

(a) Raw materials. (1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated

to an internal temperature of 38°F , or below upon receipt and shall be maintained at that temperature until the fish are to be processed.

(4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.

(b) *Defrosting of frozen fish.* (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:

(i) In air at 45°F , or below until other than hard frozen; or

(ii) In air so that the temperature in any part of the fish does not exceed 45°F ; or

(iii) In a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45°F .

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are completely defrosted.

(3) Fish entering the thaw tanks shall be free of exterior packaging material and substantially free of liner material.

(4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.

(c) *Presmoking operation.* (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous water spray or a continuous waterflow system.

(3) All fish shall be brined in a solution that does not exceed 38°F , or dry-salted at a temperature not to exceed 38°F , throughout the fish.

(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d) (2) (i) of this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d) (2) (ii) of this section.

(5) Fish shall be rinsed with fresh water after brining.

(d) *Heating, cooking, smoking operation.* (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

(i) Not less than 180°F for a minimum of 30 minutes for hot-process

smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (i) of this section, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150°F for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (ii) of this section.

(e) *Packing.* (1) The finished product shall be handled only with clean, sanitized hands, gloves, or utensils.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to a temperature of 50°F , or below within 3 hours after cooking and further cooled to a temperature of 38°F , or below within 12 hours after cooking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38°F , or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify at least the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification (i) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish and (ii) of the distribution of the finished product.

(f) *Testing.* (1) Microbiological examination of in-line and finished product samples should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

(2) The finished product shall be analyzed chemically with sufficient frequency to assure that the required salinity is obtained in every fish and that other chemical additives are present at authorized levels.

Effective date. This order shall become effective 30 days after its date of publication in the Federal Register.

Dated: November 2, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[F.R. Doc. 70-15269; Filed, Nov. 12, 1970; 8:46 a.m.]

SUBCHAPTER C—DRUGS

PART 148c—COLISTIN

Effective on publication in the Federal Register, Part 148c is republished as follows to incorporate editorial and